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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,112	BARTHOLOMAUS ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,7,8,27-29,31,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7,8,27-29,31,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1,2,4,7,8,27-29,31,41 and 42 are pending in the application. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

1. Applicant's arguments filed 10/26/10 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1,2,4,7,8,27-29,31,41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 2003/0064099A1) in view of Zhang et al. (*Pharm. Dev. Tech.* **1999**, *4*, 241-250) and in further view of Kumar et al. (US 6,238,697B1) and DeJong (*Pharmaceutisch Weekblad Scientific Edition* **1987**, p24-28) as stated in the office action mailed 6/16/10.

4. Applicant asserts that Applicant's dosage form is a sintered mass, and neither Oshlack nor any of the other references cited by the Examiner teaches or suggests anything about preparing a dosage form as a sintered mass. Hawley's Condensed Chemical Dictionary, Thirteenth Edition, defines "sintering"

as: The agglomeration of metal or earthy powders at temperatures below the melting point. Occurs in both powder metallurgy and ceramic firing. While heat and pressure are essential, decrease in surface area is the critical factor. Sintering increases strength, conductivity and density.

5. Oshlack et al. teaches of the use of a melt-extrusion technique comprising a powdered drug wherein the melt-extruded matrix (e.g. sustained release material, binder, etc.) is provided in a homogenous mixture, then heated to a temperature sufficient to at least soften the mixture and is extruded (p9, [0111]; p10, [0113]).

6. The Merriam-Webster Dictionary defines agglomeration as: the action of process of collecting in a mass.

7. Therefore, the melt-extrusion technique of Oshlack et al. encompasses the sintered mass of the instant claims as Oshlack et al. melts a homogenous powder mixture to a temperature sufficient to at least soften the mixture for the melt-extrusion technique and thus collects the homogenous powder mixture in a mass.

8. Applicant asserts that the examiner has not shown anything that would even remotely suggest that anything could be learned from any of the references cited could ever lead to a sintered dosage form.

9. The reference of Zhang et al. was not explicitly used to teach of a sintered dosage form but was used to teach of the preparation of stabilized sustained release tablets prepared by hot-melt extrusion and the PEO drug carrier of molecular weight 1,000,000 and 7,000,000 has been used to prepare sustained release tablets prepared by hot-melt extrusion. During the hot-melt extrusion process, a dry powder blend of

drug, polymer and other adjuvants were fed into the extruder and melted inside the barrel of the machine, the molten mass was extruded through a rod-shaped die and then cut manually into tablets. Thus, a powder blend of drug, PEO, etc. is melted, collected into a mass and extruded and encompasses sintering.

10. The reference of Kumar et al. was not used to teach of a sintered dosage form but was used to teach of the use of high molecular weight PEO (to bind the powder particles together) for extended release dosage forms in an amount of from about 10 to about 20 percent by weight, to provide for a hard, chip-resistant tablet wherein the polyethylene oxide allows for the slow diffusion of an active agent. The molecular weight of the polyethylene oxide is most preferably about 5,000,000 and can be varied depending on the dosage size and desired rate of release.

11. At the time of the invention it would have been obvious to one skilled in the art that the sustained release dosage forms of the combined references of Oshlack et al. and Zhang et al. contains a high molecular weight PEO polymer in an amount sufficient to result in a breaking strength of at least 500N as Kumar et al. teaches that tablets comprising high molecular weight PEO binders from about 10 to about 20 percent by weight to provide for a hard, chip-resistant tablet and allows for the slow diffusion of an active agent.

12. Applicant asserts that those skilled in the art would recognize that sintering can not take place in Oshlack's twin screw extruder, with counter-rotating intermeshing screws, and nothing in Oshlack et al. would even suggest that sintering would be

possible in such equipment. Agglomeration would not occur in a twin extruder, with counter-rotating intermeshing screws.

13. First, Oshlack et al. teaches of the use of an extruder, one example is a twin screw extruder.

14. Oshlack et al. teaches of the use of a melt-extrusion technique comprising a powdered drug wherein the melt-extruded matrix (e.g. sustained release material, binder, etc.) is provided in a homogenous mixture, then heated to a temperature sufficient to at least soften the mixture and is extruded (p9, [0111]; p10, [0113]).

15. Merriam-Webster Dictionary defined agglomeration as: the action of process of collecting in a mass.

16. Therefore, the melt-extrusion technique of Oshlack et al. encompasses the sintered mass of the instant claims as Oshlack et al. melts a homogenous powder mixture to a temperature sufficient to at least soften the mixture for the melt-extrusion technique and thus collects the homogenous powder mixture in a mass.

17. Applicant asserts that Oshlack et al. relates to fundamentally different technology. The Oshlack et al. references pertains to a controlled release dosage form which includes, as the primary defense against abuse, aversive agents, such as a bittering agent or a viscosity increasing agent, which make abuse unpleasant, but do not in any way render the dosage form abuse-proofed. Oshlack contemplates that his dosage forms may be crushed or chewed. See paragraphs [0067 - 0068], where it is disclosed that Oshlack's aversive agents are "released" when the dosage form is e.g. chewed. Thus, Oshlack discourages, but does not necessarily prevent abuse.

Oshlack's dosage forms must be tampered with in order to perform their intended function, i.e., to release the aversive agents. If somehow Oshlack's dosage forms were rendered crush-proof, as Applicants' dosage forms are, then Oshlack's point of novelty would be destroyed, and his dosage forms could not perform their intended function.

18. The reference of Oshlack et al. teaches that the aversive agent is released when the dosage form is tampered with and describes such tampering includes dissolution in a solvent, heating, etc. which do not require chewing or crushing, etc. and therefore the dosage forms are not necessarily chewed or crushed to release the "aversive agent".

19. Applicant asserts that the composition that is melt extruded in paragraph [0111] does not comprise Applicant's polyalkylene oxide (C).

20. The reference of Oshlack et al. was not used to teach of polyalkylene oxide (C) but was used to teach of a melt-extruded matrix comprising an opioid, sustained release material, binder, etc. provided in a homogenous mixture. The extrudate provides sustained release of the opioid analgesic for a time period of at least about 12 hours wherein the sustained-release profile of the melt-extruded formulations of the invention can be altered by varying the amount of sustained-release material, etc.

21. The reference of Zhang et al. was used to teach of the preparation of stabilized sustained release tablets prepared by hot-melt extrusion and that the PEO drug carrier of molecular weight 1,000,000 and 7,000,000 has been used to prepare sustained release tablets prepared by hot-melt extrusion.

22. The reference of Kumar et al. was used to teach of the use of high molecular weight PEO (to bind the powder particles together) for extended release dosage forms

in an amount of from about 10 to about 20 percent by weight, to provide for a hard, chip-resistant tablet wherein the polyethylene oxide allows for the slow diffusion of an active agent. The molecular weight of the polyethylene oxide is most preferably about 5,000,000 and can be varied depending on the dosage size and desired rate of release.

23. The reference of DeJong was used to teach of the calculation for determining crushing strength wherein the comparison of specific crushing strength with other tablet dimensions can be determined.

24. At the time of the invention it would have been obvious to one skilled in the art that the sustained release dosage forms of the combined references of Oshlack et al. and Zhang et al. contains a high molecular weight PEO polymer (sustained release material) in an amount sufficient to result in a breaking strength of at least 500N as Kumar et al. teaches that tablets comprising high molecular weight PEO binders from about 10 to about 20 percent by weight to provide for a hard, chip-resistant tablet and allows for the slow diffusion of an active agent. DeJong teaches shows the relationships between specific crushing strength, porosity, friability and disintegration time, than can be described in simple mathematical form.

25. Applicant asserts that the only disclosure of polyalkylene oxide in Oshlack et al. is exclusively concerned with osmotic dosage forms, which, however, are not sintered. Oshlack et al. mentions methods for the preparation of matrix formulations which methods may be regarded as thermoforming, such as melt-extrusion. The matrix materials according to Oshlack et al., however, do not encompass polyalkylene oxide.

26. The reference of Oshlack et al. was not used to teach of polyalkylene oxide (C).

27. Applicant asserts that Oshlack et al. does not rely on a controlled-release matrix, but on the expansion of the waterswellable high molecule polyalkylene oxide in the push layer, which does not contain the drug.

28. The reference of Oshlack et al. was not used to teach of polyalkylene oxide (C) and the recitation of "the expansion of the waterswellable high molecule polyalkylene oxide in the push layer" is in regards to osmotic dosage forms which was not used to formulate the rejection.

29. The reference of Oshlack et al. was used to teach of matrix formulations, such as sustained release formulations that comprise an opioid analgesic, sustained release material, aversive agent, etc.

30. The reference of Zhang et al. was used to teach of the preparation of stabilized sustained release tablets prepared by hot-melt extrusion. The sustained release tablets prepared by hot-melt extrusion comprise polyethylene oxide (PEO) polymers of molecular weight 1,000,000 and 7,000,000 in the matrix tablet as PEO was shown to be a suitable polymeric drug carrier for this process.

31. The reference of Kumar et al. was used to teach of extended release dosage forms which comprise high molecular weight polyethylene oxide binder (to bind the powder particles together), in an amount of from about 10 to about 20 percent by weight wherein the polyethylene oxide allows for the slow diffusion of an active agent.

32. At the time of the invention it would have been obvious to one skilled in the art to use the PEO of high molecular weight of Zhang et al. for the sustained release dosage forms of Oshlack et al. as the disclosures are drawn to the same utility, such as

sustained release dosage forms having sustained release material, such as PEO of Zhang et al. which are used for the preparation of melt-extruded tablets via a melt-extrusion technique.

33. At the time of the invention it would have been obvious to one skilled in the art that the sustained release dosage forms of the combined references of Oshlack et al. and Zhang et al. contains a high molecular weight PEO polymer in an amount sufficient to result in a breaking strength of at least 500N as Kumar et al. teaches that tablets comprising high molecular weight PEO binders from about 10 to about 20 percent by weight to provide for a hard, chip-resistant tablet and allows for the slow diffusion of an active agent.

34. Applicant asserts that Oshlack et al. mentions the use of polyethylene oxide having a molecular weight of 1-15 million. As can be seen from the previously submitted product description sheets the chemical supplier SIGMA-ALDRICH® commercializes polyethylene oxides having molecular weights of 10,000 g/mol and 100,000 g/mol, respectively, i.e. molecular weights which are 10 times and 100 times lower than the lower limit according to the instant claim 1. Accordingly, Oshlack's disclosure of the use of polyethylene oxide as a gelling agent does not teach or suggest anything about the inclusion of polyethylene oxide in the 1-15 million molecular weight range as a hardening agent. The entire section dealing with matrix formulations is completely silent on polyalkylene oxide having a molecular weight of 1-15 million g/mol.

35. The reference of Oshlack et al. was not used to teach of polyalkylene oxide (C) but was used to teach of a melt-extruded matrix comprising an opioid, sustained release

material, binder, etc. is provided in a homogenous mixture. The extrudate provides sustained release of the opioid analgesic for a time period of at least about 12 hours wherein the sustained-release profile of the melt-extruded formulations of the invention can be altered by varying the amount of sustained-release material, etc.

36. The reference of Zhang et al. was used to teach of the preparation of stabilized sustained release tablets prepared by hot-melt extrusion. The sustained release tablets prepared by hot-melt extrusion comprise polyethylene oxide (PEO) polymers of molecular weight 1,000,000 and 7,000,000 in the matrix tablet as PEO was shown to be a suitable polymeric drug carrier for this process.

37. The reference of Kumar et al. was used to teach of extended release dosage forms which comprise high molecular weight polyethylene oxide binder (to bind the powder particles together/hardening agent), in an amount of from about 10 to about 20 percent by weight wherein the polyethylene oxide allows for the slow diffusion of an active agent.

38. At the time of the invention it would have been obvious to one skilled in the art to use the PEO of high molecular weight of Zhang et al. for the sustained release dosage forms of Oshlack et al. as the disclosures are drawn to the same utility, such as sustained release dosage forms having sustained release material, such as PEO of Zhang et al. which are used for the preparation of melt-extruded tablets via a melt-extrusion technique, which encompasses the sintering technique of the instant claims which recites press-forming with preceding exposure to heat.

39. At the time of the invention it would have been obvious to one skilled in the art that the sustained release dosage forms of the combined references of Oshlack et al. and Zhang et al. contains a high molecular weight PEO polymer in an amount sufficient to result in a breaking strength of at least 500N as Kumar et al. teaches that tablets comprising high molecular weight PEO binders from about 10 to about 20 percent by weight to provide for a hard, chip-resistant tablet and allows for the slow diffusion of an active agent.

40. Applicant asserts that there is nothing in the reference that would teach or suggest anything about the possibility of achieving a breaking strength of at least 500 N, under any circumstances, let alone hint that this could be achieved by including a sufficient amount of polyalkylene oxide and sintering.

41. The reference of Oshlack et al. was not explicitly used to teach of a breaking strength of at least 500 N but was used to teach of a melt-extruded matrix comprising an opioid, sustained release material, binder, etc. is provided in a homogenous mixture. The extrudate provides sustained release of the opioid analgesic for a time period of at least about 12 hours wherein the sustained-release profile of the melt-extruded formulations of the invention can be altered by varying the amount of sustained-release material, etc.

42. The reference of Zhang et al. was used to teach of the preparation of stabilized sustained release tablets prepared by hot-melt extrusion and that the PEO drug carrier of molecular weight 1,000,000 and 7,000,000 has been used to prepare sustained release tablets prepared by hot-melt extrusion.

43. The reference of Kumar et al. was used to teach of the use of high molecular weight PEO (to bind the powder particles together) for extended release dosage forms in an amount of from about 10 to about 20 percent by weight, to provide for a hard, chip-resistant tablet wherein the polyethylene oxide allows for the slow diffusion of an active agent. The molecular weight of the polyethylene oxide is most preferably about 5,000,000 and can be varied depending on the dosage size and desired rate of release.

44. The reference of DeJong was used to teach of the calculation for determining crushing strength wherein the comparison of specific crushing strength with other tablet dimensions can be determined.

45. At the time of the invention it would have been obvious to one skilled in the art that the sustained release dosage forms of the combined references of Oshlack et al. and Zhang et al. contains a high molecular weight PEO polymer in an amount sufficient to result in a breaking strength of at least 500N as Kumar et al. teaches that tablets comprising high molecular weight PEO binders from about 10 to about 20 percent by weight to provide for a hard, chip-resistant tablet and allows for the slow diffusion of an active agent. DeJong teaches shows the relationships between specific crushing strength, porosity, friability and disintegration time, than can be described in simple mathematical form.

46. Applicant asserts that Zhang et al. uses PEO as a drug carrier which is completely different than Oshlack's use of polyethylene oxide as a hydrogel, as described in paragraph [0150] or as a "push layer" as described in paragraph [0151]. Nothing in either of these references would teach or suggest that Oshlack's dosage

form should be modified to include 74-88% PEO of a molecular weight 1,000,000 and 7,000,000. The maximum molecular weight of the PEO used by Oshlack et al. as a hydrogel is 750,000.

47. The reference of Oshlack et al. was not used to teach of polyalkylene oxide (C) but was used to teach of a melt-extruded matrix comprising an opioid, sustained release material, binder, etc. is provided in a homogenous mixture. The extrudate provides sustained release of the opioid analgesic for a time period of at least about 12 hours wherein the sustained-release profile of the melt-extruded formulations of the invention can be altered by varying the amount of sustained-release material, etc.

48. The reference of Zhang et al. was used to teach of the preparation of stabilized sustained release tablets prepared by hot-melt extrusion. The sustained release tablets prepared by hot-melt extrusion comprise polyethylene oxide (PEO) polymers of molecular weight 1,000,000 and 7,000,000 in the matrix tablet as PEO was shown to be a suitable polymeric drug carrier for this process.

49. The reference of Kumar et al. was used to teach of extended release dosage forms which comprise high molecular weight polyethylene oxide binder (to bind the powder particles together/hardening agent), in an amount of from about 10 to about 20 percent by weight wherein the polyethylene oxide allows for the slow diffusion of an active agent.

50. The reference of DeJong was used to teach of the calculation for determining crushing strength wherein the comparison of specific crushing strength with other tablet dimensions can be determined.

51. At the time of the invention it would have been obvious to one skilled in the art to use the PEO of high molecular weight of Zhang et al. for the sustained release dosage forms of Oshlack et al. as the disclosures are drawn to the same utility, such as sustained release dosage forms having sustained release material, such as PEO of Zhang et al. which are used for the preparation of melt-extruded tablets via a melt-extrusion technique, which encompasses the sintering technique of the instant claims which recites press-forming with preceding exposure to heat.

52. At the time of the invention it would have been obvious to one skilled in the art that the sustained release dosage forms of the combined references of Oshlack et al. and Zhang et al. contains a high molecular weight PEO polymer in an amount sufficient to result in a breaking strength of at least 500N as Kumar et al. teaches that tablets comprising high molecular weight PEO binders from about 10 to about 20 percent by weight to provide for a hard, chip-resistant tablet and allows for the slow diffusion of an active agent. DeJong teaches shows the relationships between specific crushing strength, porosity, friability and disintegration time, than can be described in simple mathematical form.

53. The instant claims do not recite, "include 74-88% PEO of a molecular weight 1,000,000 and 7,000,000" but recite "component (C) is present in an amount of at least 30 wt.-%."

54. In regards to the amount of PEO, such as of at least 30 wt%, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired

properties such as the desired (ratios, concentrations, percentages, etc.) as Oshlack et al. teaches that melt-extruded formulations of the invention can be altered by varying the amount of sustained-release material, etc. to provide for the sustained release of the drug over at least 12 hours and Kumar et al. teaches that PEO may be included in a dosage form in an amount of from about 10 to about 20 percent by weight but be varied depending on the dosage size and desired rate of release. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

55. Applicant asserts that nothing in either Kumar et al. or DeJong could possibly compensate for the deficiencies of Oshlack et al. and Zhang et al. with respect to the absence of anything that would teach or suggest the preparation of a sintered mass dosage form, or any other dosage form configuration that would have a breaking strength of at least 500 N.

56. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

57. Applicant asserts that nothing in Kumar et al. teaches or suggests any tablet having a crushing strength of at least 500 N. Kumar's chip-resistance has nothing to do with crushing strength.

58. The reference of Kumar et al. was not explicitly used to teach of a breaking strength of at least 500 N but was used to teach of extended release dosage forms which comprise high molecular weight polyethylene oxide binder (to bind the powder particles together/hardening agent), in an amount of from about 10 to about 20 percent by weight wherein the polyethylene oxide allows for the slow diffusion of an active agent and to provide for a hard, chip-resistant tablet.

59. The reference of DeJong was used to teach of the calculation for determining crushing strength wherein the comparison of specific crushing strength with other tablet dimensions can be determined.

60. At the time of the invention it would have been obvious to one skilled in the art that the sustained release dosage forms of the combined references of Oshlack et al. and Zhang et al. contains a high molecular weight PEO polymer in an amount sufficient to result in a breaking strength of at least 500N as Kumar et al. teaches that tablets comprising high molecular weight PEO binders from about 10 to about 20 percent by weight to provide for the slow diffusion of an active agent and a hard, chip-resistant tablet and DeJong teaches shows the relationships between specific crushing strength, porosity, friability and disintegration time, than can be described in simple mathematical form. The recitation of PEO binders from about 10 to about 20 percent by weight encompasses the amount of at least 30 wt.-% of the instant claims and therefore the tablets of the combined disclosure are capable of the same functions and properties, such as a breaking strength of at least 500 N wherein DeJong teaches of the method for mathematically determining crushing strength.

Conclusion

61. No claims are allowed at this time.

62. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618